

- 7 -

Commissioner of Patents and Trademarks

09/980,163

### R E M A R K S

With regard to the informalities, the following amendments have been made:

Page 9,      line 7      the phrase "a goal function in term of property weighted deviations" has been amended to "a goal function in terms of property deviation.

Page 10,      line 9      the term "between" has been amended to "using".  
                  line 10      "module 14 shown in Fig. 2" has been changed to "module 14 shown in Fig. 1".

                  line 11      "step 40" has been changed to "step 40 in Fig. 2".

With regards to the phrase at page 10, lines 20-22, Applicant disagrees that it is incorrect and accordingly no changes have been made.

Page 15,      line 27      "factor" has been changed to "property".  
Page 16,      line 3      "factor" has been changed to "property".  
                  line 10      "property" has been changed to "parameter".

With regards to Table 1 at page 18, Applicant submits that the experimental runs were selected to test the invention and may include identical runs for reproducibility testing purposes. Applicant does not fully understand what is meant by the statement "this does not agree with what is claimed" made by the Examiner.

Clarification is respectfully requested.

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- 8 -

Commissioner of Patents and Trademarks

09/980,163

Page 18, line 13 the phrase "could be responsible of the appearance" has been amended to "could be responsible for the appearance".

With regards to page 21, line 8, "since n = 3<8" refers to sub-step 1) at page 12, line 13.

Applicants believe that these amendments should overcome the informality objections. However, if the amendments are not entirely satisfactory, the Examiner is kindly requested to specify which further corrections are needed.

Applicant would like to thank the Examiner for his review of the application. The Examiner has indicated to Applicant that he was comfortable with the technical content of the application. Accordingly, Applicant will not provide a detailed explanation of the scope of the claims. However if, after consideration of the arguments provided below, the Examiner feels that certain aspects of the application or of Applicant's arguments require clarification, he is urged to communicate with the agent of record listed above.

The examiner has rejected claims 25, 26 and 34-36 under 35 USC 103(a) on the ground that they are unpatentable over Mozzo in view of Martin and Lemelson. The rejection is respectfully traversed.

The Examiner's contention is that Mozzo teaches establishing property behaviour mathematical relations and a goal function but does not teach weighting of properties  $Y_j$  for use in the goal function. Examiner argues that using weighting of properties  $Y_j$  is taught by Martin.

- 9 -

Commissioner of Patents and Trademarks

09/980,163

Applicant would like to point out some fundamental differences between the method of the present application and that of Mozzo that will reveal that the teachings of Mozzo and Martin (and Lemelson) are different from the present invention and that the present invention would not be obvious to one of ordinary skill in the art in view of the cited prior art.

According to the method of Mozzo, from a set of property relations expressed in terms of parameters which is obtained by standard statistical methods using the results of a number of experimental runs of the process, a corresponding set of property relations expressed in terms of weighted parameters is derived. For each actual value of a parameter, a first weighting is expressed as the ratio of: (a) the deviation of the actual value from the mean value of the parameter over the experimental range, on (b) the range between extreme values for that parameter over the experimental range. Then, a goal function is established in term of deviations between weighted values of property values as estimated by the property relations and corresponding weighted values of specified goal values for the properties. For each goal value of a property, a second weighting is expressed as the ratio of: (a) the deviation of the actual value from the mean value of the property over the experimental range, on (b) the range between extreme values for that property over the experimental range. Then, according to a recursive geometric algorithm aimed at successively minimizing the established goal function, a set of optimal parameter values is generated.

- 10 -

Commission r of Patents and Trademarks

09/980,163

The "weightings" as taught by Mozzo do not reflect the relative importance of the properties involved but rather reflect the difference in the value of the parameter or property from the mean value of a set of parameter or property values.

This is in sharp contrast to the instant invention wherein the weighting reflects the relative importance of the properties  $Y_j$  for the characterization of the product as claimed in claim 25 ("assigning values to a set of k property weights  $w_j$  representing relative importance of said properties  $Y_j$  for the characterization of said product"). Applicant further submits that Martin does not teach or suggest the application of the weighting described therein (column 15 line 23) to the goal function of Mozzo in such a way that would be equivalent to the method of as claimed in claim 25 of the present invention. First of all Martin's teaching relates to dynamic systems of signals which in itself is a completely different context than that of the present invention which does not relates to dynamic (time dependent) functions. Furthermore, the weighting as taught in Martin is for the purpose of reducing the error between the predicted process behaviour  $y^P(t)$  and the desired process behaviour  $y^d(t)$  at certain time intervals (see column 15 lines 25-63). In this respect Martin at column 15 line 26 to 30 states:

"The present utilizes ..."trajectory weighting" which encompasses the concept that one does not put a constant degree of importance on the future predicted process behaviour matching the desired behaviour at every future time set..."  
(our underlining)

- 11 -

Commissioner of Patents and Trademarks

09/980,163

Clearly, Martin suggests weighting for the purpose of reducing the error between the predicted and desired behaviour as a function of time which is quite different from the weighting of the present invention which purpose is to reflect the relative importance of a property on a characteristic of the product as clearly specified in claim 25 ("assigning values to a set of k property weights  $w_j$  representing relative importance of said properties  $Y_j$  for the characterization of said product"). Thus even if one were to apply the weighting of Martin to Mozzo, which is not suggested by Martin, it would lead to the necessity of determining the extent of the difference between a given desired property and the corresponding predicted property in order to determine the weight value. In other words, the choice of the weight factor would have to be function of the difference between the  $v_j$  and  $v_j^*$ . This is completely incompatible with the present method where the weight factor is determined even before any behaviour function is established. Furthermore it is unclear what the effect of a weight factor would have on the convergence of  $\delta^2$  in Mozzo since the properties (and the parameters) are already "weighted" relative to the mean and the spread of the data. Therefore it would not be obvious to one of ordinary skill in the art to combine Mozzo and Martin to arrive at the method of claim 25.

Furthermore, the Examiner contends that Lemelson teaches minimization of goal function to generate n optimal parameters values for the parameters  $X_i$ . Even if Mozzo and Martin would teach the previous steps, which they do not, Lemelson would not make the step of generating n optimal parameters obvious in the context of the present invention. Lemelson teaches the selection of the "best of the predicted outcomes" in the sense of minimizing the goal function. However, the selection of the "n optimal parameters" in Lemelson is done by an iterative process (see figure 3 in Lemelson) in which the "optimized" parameters are used in the process to

- 12 -

Commissioner of Patents and Trademarks

09/980,163

generate a new coating image and the optimization of the objective function is repeated. Thus Lemelson does not arrive at the n optimal parameters as taught in the present invention in which the determination of the optimal parameters depends on the weighting values of the properties. In other words, the assignment of weight values to the properties as per the first step of claim 25, influences the determination of the n optimal parameters. Thus it can be argued that the set of optimal parameter values as taught by Lemelson is not necessarily equivalent to the set of optimal parameters derived using the method of the present invention. Therefore and in view of the above arguments, it is respectfully submitted that claim 25 is not rendered obvious in further view of Lemelson.

With regards to claim 26, while Mozzo also teaches that the product is a composition of matter, the set of optimal parameters is clearly obtained using a different method as explained supra.

With regards to claim 34 it is respectfully submitted that the goal function of Martin is summed over a time interval (in addition to the summation over the j control variables) and that the weighting is for a different purpose as explained supra. Thus insofar as claim 34 depends on claim 25 and in view of the above arguments the claim is not obvious in view of Martin.

Claim 35 ultimately depends on claim 25 and as such, based on the above arguments, it is not obvious in view of the cited art. Furthermore, the successive iterations of Mozzo are based on a recursive geometric (generation of hypercubes) algorithm aimed at successively minimizing the established goal function. There is no such geometric algorithm in the present invention and when the claim is read in

- 13 -

Commissioner of Patents and Trademarks

09/980,163

view of the disclosure, one skilled in the art would appreciate that no such geometric algorithm is used for the successive iterations as specified in claim 35.

Claim 36 depends on claim 35 (and ultimately on claim 25) and as such is not obvious based on the arguments provided above.

The Examiner has rejected claim 27 under 35 USC 103(a) on the ground that it is unpatentable over Mozzo in view of Martin and Lemelson and in further view of Huse et al. The rejection is respectfully traversed.

Claim 27 ultimately depends on claim 25 and it has been demonstrated above that claim 25 is not obvious in view of Mozzo, Martin and Lemelson. Furthermore Huse et al. does not teach or suggest "optimal parameters...characterizing...the pharmaceutical product" in the context of the method of the present invention. Huse et al. fail to suggest a set of optimal parameters in the sense of optimizing certain properties of a product. Huse et al. teach a method that simulates product chemicals in terms of how they are made and their biological effect.

The examiner has rejected claims 28 and 37-39 under 35 USC 103(a) on the ground that they are unpatentable over Mozzo in view of Martin and Lemelson in further view of Lobleby et al. The rejection is respectfully traversed.

Claim 28 ultimately depends on claim 25 and it has been demonstrated above that claim 25 is not obvious in view of Mozzo, Martin and Lemelson. As such claim 28 is not obvious even when it is specified that the  $w_j$  are obtained by AHP. Similarly claims 37-39 ultimately depend on claim 25 and it has been demonstrated above that

- 14 -

Commissioner of Patents and Trademarks

09/980,163

claim 25 is not obvious in view of Mozzo, Martin and Lemelson. Furthermore it is pointed out that there is no step of weighting of the factors (optimal parameters) in claims 28 and 37-39 thus applicant does not agree that the teaching of Loble et al. can be taken in conjunction with the other cited prior art to arrive at the claims.

The examiner has rejected claims 29 under 35 USC 103(a) on the ground that they are unpatentable over Mozzo in view of Martin and Lemelson in further view of Loble et al. and Li. The rejection is respectfully traversed.

Claim 29 depends on claim 28 and ultimately depends on claim 25 and it has been demonstrated above that claim 25 is not obvious in view of Mozzo, Martin and Lemelson and claim 28 is not obvious in further view of Loble. Thus claim 29 even in further view of Li is not obvious.

The examiner has rejected claims 30 under 35 USC 103(a) on the ground that they are unpatentable over Mozzo in view of Martin, Lemelson, Loble and Li and in further view of NIST. The rejection is respectfully traversed.

Claim 30 depends on claim 29 and ultimately depends on claim 25 and it has been demonstrated above that claim 25 is not obvious in view of Mozzo, Martin and Lemelson and claim 29 is not obvious in further view of Loble and Li. Thus claim 30, even in further view of NIST, is not obvious.

The examiner has rejected claim 31 under 35 USC 103(a) on the ground that they are unpatentable over Mozzo in view of Martin, Lemelson and Huse et al. and in further view of Loble et al. The rejection is respectfully traversed.

- 15 -

Commissioner of Patents and Trademarks

09/980,163

Claim 31 depends on claim 27 and ultimately depends on claim 25 and it has been demonstrated above that claim 25 is not obvious in view of Mozzo, Martin and Lemelson and claim 27 is not obvious in further view of Huse et al. Thus claim 31, even in further view of Lobley et al., is not obvious.

The examiner has rejected claim 32 under 35 USC 103(a) on the ground that they are unpatentable over Mozzo in view of Martin, Lemelson and Huse et al. in further view of Lobley et al and Li. The rejection is respectfully traversed.

Claim 32 depends on claim 31 and ultimately depends on claim 25 and it has been demonstrated above that claim 25 is not obvious in view of Mozzo, Martin and Lemelson and claim 31 is not obvious in further view of Lobley. Thus claim 32 even in further view of Li is not obvious.

The examiner has rejected claims 33, 43, 46, 50 and 51 under 35 USC 103(a) on the ground that they are unpatentable over Mozzo in view of Martin, Lemelson, Lobley et al., Huse et al. and Li and in further view of NIST. The rejection is respectfully traversed.

These claims 30 ultimately depends on claim 25 and it has been demonstrated above that claim 25 is not obvious in view of Mozzo, Martin and Lemelson. Thus the claims, even in further view of Lobley et al., Huse et al., Li and NIST, are not obvious.

- 16 -

Commissioner of Patents and Trademarks

09/980,163

The examiner has rejected claims 40 and 44 under 35 USC 103(a) on the ground that they are unpatentable over Mozzo in view of Martin, Lemelson and Li and in further view of NIST. The rejection is respectfully traversed.

Claim 40 is an independent claim similar in scope to claim 25 but incorporating subject matter of claims dependent on claim 25. In particular it is specified that the parameters  $X_i$  and the properties  $Y_j$  are obtained with  $l$  experimental runs. As such, and for the reasons given in the arguments *supra*, it is respectfully submitted that the claim is not obvious in view of the cited prior art.

Similarly, claim 44 as it depends on claim 40 is deemed not obvious.

Finally, The examiner has rejected claims 41, 42, 45, 47-49 and 52 under 35 USC 103(a) on the ground that they are unpatentable over Mozzo in view of Martin, Lemelson, Huse et al and Li and in further view of NIST. The rejection is respectfully traversed.

These claims are similar in scope to claim 25 and claims dependent thereof. As such, and for the reasons given in the arguments *supra*, it is respectfully submitted that the claim is not obvious in view of the cited prior art.

- 17 -

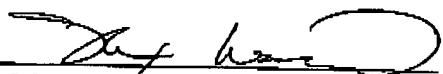
Commissioner of Patents and Trademarks

09/980,163

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